JUL - 5 2001

K011436

010

510(k) Summary of Safety and Effectiveness

May 8, 2001

Submitter

VitalCom Inc.
15222 Del Amo Avenue
Tustin, CA, 92780
USA

Telephone: (714) 546-0147
Fax: (714) 247- 4030

Contact: Ms. Florin Truuvert, Regulatory Affairs Manager

Device Name

Trade Name:	Mobile-PatientViewer™
Common Name:	Patient Data Viewer
Classification Name:	An accessory to an Echocardiograph Monitor Electrocardiograph – 21 CFR 870.2340, Product Code 73DPS.
Classification:	Mobile PatientViewer is an accessory to the Class II, Echocardiograph Monitor

Predicate Device

The predicate device is the VitalCom Remote Viewing Station, RVS (K962473).

Device Description

The Mobile-PatientViewer™, also referred to as MPV, is a wireless hand-held PC-based data viewer that allows physicians and caregivers to have instant remote access to their patients' data from anywhere within the hospital enterprise at any time. The MPV use a proprietary software application program operating on off-the-shelf computers operating under Windows CE or Windows for Pocket PC that supports an IEEE 802.11 wireless LAN.

Indications for Use

The Mobile-PatientViewer is intended to be used by physicians and caregivers to view physiological data and alarm status of those patients being monitored by the PatientNet Central Station, also known as VCOM. The MPV is intended for use from any location within a hospital enterprise.

The MPV is available for sale only upon the order of a physician or licensed health care professional.

Comparison to the Predicate Device

It is VitalCom's conclusion that the Mobile-PatientViewer is substantially equivalent to the Remote Viewing Station (RVS).

- Both MPV and RVS are viewing stations only. The user can not change patient settings. They are read-only monitors.
- Both provide the ability to continuously view a patient's current data (such as physiologic waveforms and other numerical vital sign values), event historical waveform data, and retrospective trended patient data.
- While the RVS is directly connected to the PatientNet Real-Time Network via a proprietary Ethernet LAN. The MPV is connected to the PatientNet Real-Time Network via a wireless LAN connection with the VitalCom Network Data Server (VNDS) which in turn is directly connected to the PatientNet Real Time Network.
- The RVS can be configured to display 8 or 16 patients at a time, whereas the MPV displays one patient at a time.
- Both MPV and RVS operate on off-the-shelf PC-based hardware.

Summary of Performance Testing

The Mobile-PatientViewer has been tested and found to comply with the design control requirement of the 21CFR 820.30 and the product specification listed in the labeling.

The risk analysis, identifying potential hazards and documenting mitigation of hazards has been developed, verified and validated as part of VitalCom's product development and design control procedure. VitalCom Quality System conforms to 21CFR820 and is certified by Intertek Testing Services (ITS) to ISO 9001 standard.

Conclusions
As stated above, VitalCom's conclusion is that the Mobile PatientViewer is safe, effective, complies with the appropriate medical device and information technology standards, and is substantially equivalent to the VitalCom Remote Viewing Station (RVS).

This 510(k) Summary of Safety and Effectiveness may be copied and submitted to interested parties as required by 21CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2001

Ms. Florin Truuvert
Regulatory Affairs Manager
VitalCom Inc.
15222 Del Amo Ave.
Tustin, CA 92780

Re: K011436
Trade Name: Mobile-PatientViewer™
Regulation Number: 870.2340
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: May 8, 2001
Received: May 10, 2001

Dear Ms. Truuvert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you

might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

Applicant
VitalCom, Inc.
15222 Del Amo Avenue
Tustin, CA, 92780
USA

Telephone: (714) 546-0147
Fax: (714) 247- 4030
510(k) Number: K011436

Device Name: Mobile Patient Viewer™

Indication for Use:
The Mobile Patient Viewer, MPV is a Pocket PC-based wireless hand-held personal patient data viewer which allows physicians and caregivers to have instant remote access to their patients' data from anywhere within the hospital enterprise at any time. It is intended to be used by healthcare professionals and clinicians to view physiological ECG data and alarm status of those patient populations being monitored by the PatientNet Central Station.

The MPV is intended for use from any location within a hospital enterprise.

The MPV is available for sale only upon the order of a physician or licensed health care professional.

Please do not write below this line – continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21CFR801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011436